

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE BOARD OF PATENT APPEALS AND INTERFERENCES

In re:	
Applicant: Kent, et al.	
Serial No.: 09/710,633) Group Art Unit: 1654
Filed: November 8, 2000) Examiner: Russel, J.
Title: SYNTHESIS OF PROTEINS BY NATIVE CHEMICAL LIGATION)) Our Ref.: TSRI 478.0Con1)

Reply to Examiner's Answer

Mail Stop Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Responsive to the Examiner's Answer, dated 8/23/05, Applicant submits the following Reply.

Claims:

Applicant wishes to withdraw its appeal of the Examiner's final rejection of claims 12-14. These claims will be cancelled by Applicant when the application is returned to the Examiner for further processing. Applicant maintains its appeal of claims 11 and 32.

Issues:

In view of Applicant's withdrawal of its appeal of the rejection of claims 12-14, the Issue No. 5, i.e., the issues relating to the rejection of claims 12-14, becomes irrelevant and is withdrawn.

The Examiner has withdrawn Issue No. 4.

Issues No.'s 1-3 are maintained and their review is requested.

<u>Arguments</u>

<u>Issues No.'s 1-3</u>:

In the Examiner's Answer, it is admitted that Applicant's specification discloses one example of the use of the process of Claims 11 and 32 (Example 4 and Figure 9) and two generalized statements in support of said process (page 7, bottom of first paragraph and page 21, second paragraph). The Examiner alleges that this is insufficient to satisfy the written description requirement of 35 USC 112, first paragraph. The CCPA and CAFC disagree.

In re Rasmussen, 650 F.2d at 1214, 211 U.S.P.Q. at 326-27, held that a disclosure of a single example of a method of "adheringly applying" one layer to another was sufficient to support a generic claim to "adheringly applying" because one skilled in the art reading the specification would understand that it is unimportant how the layers are adhered, so long as they are adhered. The holding of *In re Rasmussen* is applicable to claims 11 and 32 of the present appeal.

In the present case, a person skilled in the art, after reviewing Applicant's written specification, including page 7, bottom of first paragraph, and page 21, second paragraph, would appreciate that amino acid substitutions or additions within either or

both of the two oligopeptides being ligated, other than at the *N*-terminal end of the second oligopeptide, were contemplated by Applicant to be within the scope of the invention and that such substitutions would be unimportant to the success of the claimed ligation process. This aspect of the subject matter of Claims 11 and 32 is described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors had possession of the claimed process of Claims 11 and 32 at the time the application was filed. There is no issue of enablement.

Furthermore, a person skilled in the art, after reviewing Applicant's written specification, including Example 4 and Figure 9, would appreciate that substituting or adding a cysteine at the *N*-terminal end of the second oligopeptide, would be essential to the success of the claimed ligation process. This aspect of the subject matter of Claims 11 and 32 is also described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors had possession of the claimed process of Claims 11 and 32 at the time the application was filed. There is no issue of enablement.

The level of skill in the art of peptide ligation is high and the claimed process of peptide ligation covered by claims 11 and 32 is predicable. A person skilled in the art would appreciate, after reviewing the specification, that the specification describes a ligation process in such a way as to reasonably convey to one skilled in the relevant art that the inventors had possession not only of a process for ligating peptides for producing "naturally isolatable proteins," but also for producing "desired proteins" having cysteines or other variant residues not present in such "naturally isolatable proteins." These "desired proteins" are made by the process covered by claims 11 and 32.

Summary:

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Applicant respectfully requests that the Board reverse the Examiner's final rejection of claims 11 and 32 under 35 U.S.C. 112, first paragraph, and the Examiner's finding that claims 11 and 32 contain subject matter which is not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors had possession of the claimed invention at the time the application was filed. Applicant further requests that the application be returned to the Examiner for further examination.

Respectfully submitted,

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